

REMARKS

The Examiner's Action mailed on January 29, 2004, has been received and its contents carefully considered.

In this Amendment, Applicant has editorially amended the specification, and canceled claims 1 and 2. These claims have been re-written as new claims 3 and 4, respectively. Claim 3 is the independent claim and claims 3 and 4 are pending in the application. For at least the following reasons, it is submitted that this application is in condition for allowance.

The Examiner's Action has rejected claims 1 and 2 as being indefinite. Because these claims have been canceled, this rejection has been rendered moot. However, in drafting claims 3 and 4, special care has been taken to ensure that these claims comply with all official provisions.

The Examiner's Action has rejected claims 1 and 2 as being obvious over *Twardowski* (USP 5,484,397) in view of *Wainwright* (USP 5,052,382). Because claims 1 and 2 have been canceled, Applicant will treat this rejection as pertaining to claims 3 and 4. It is submitted that these claims are *prima facie* patentably distinguishable over the cited references, either taken alone or in any reasonable combination, for at least the following reasons.

Applicant's independent claim 3 is directed to an ozone hemodiafiltration device. The device includes, *inter alia*, an ozone generator that converts water that is treated by reverse osmosis into an ozone water solution. The device further includes a dialysate fluid circuit that receives the ozone water solution and mixes the ozone water solution to form an aseptic isotonic solution that contains ozone, with the dialysate fluid circuit

being coupled to a dialyzer to supply the aseptic isotonic solution into the dialyzer. This claim also recites that the device includes an extracorporeal circuit that draws blood from a human body, passes the blood through the dialyzer, and then returns the blood back to the human blood vessels. Further, the device includes a replenishing solute circuit that is coupled to the dialysate fluid circuit to conduct the isotonic solution that contains ozone from the dialysate fluid circuit, and is further coupled to the extracorporeal circuit so that the isotonic solution that contains ozone is transported into the extracorporeal circuit to enter the human blood vessels so as to provide water supplement and to kill microorganisms in the human body. This claimed device is neither disclosed nor suggested by the cited references.

Twardowski discloses an artificial kidney that can be used for home dialysis and further discloses providing ozone that can be used as a disinfecting agent for cleaning and disinfecting the system after it has been used. This reference discloses that the system includes a dialysate flow path as shown in Figure 1, and a blood flow path as shown in Figure 2. This reference shows that a dialysis solution circuit 94 provides the dialysis solution to the dialyzer 100, and further discloses a blood/dialysate shunt 138 for connection with the extracorporeal blood circuit. This reference also discloses that a saline bag 164 is connected to the inflow line 144 of the extracorporeal circuit. Furthermore, a shunt valve 174 is provided which connects the outflow line 146 of the blood flow path with the dialysate tubing 118 using the blood/dialysate shunt 138. This reference further discloses that the shunt valve 174 allows fluids to pass from the extracorporeal blood circuit and into the dialysate tubing 118, but prevents fluid passage in the opposite direction.

However, and in contrast to the present invention, this reference does not disclose or otherwise suggest a replenishing solute circuit that is coupled to both a dialysate fluid circuit and to an extracorporeal circuit, so that isotonic solution that contains ozone is transported into the extracorporeal circuit to enter the human blood vessels, as recited by Applicant's independent claim 3. In fact, it is noted that the Examiner's Action has not even addressed Applicant's claimed replenishing solute circuit in the rejections.

Furthermore, this reference does not disclose or otherwise suggest transporting ozone into an extracorporeal circuit to enter human blood vessels to kill microorganisms in the human body, as recited by claim 3. Instead, this reference only teaches utilizing ozone as a disinfecting agent of a medical device, after the medical device has been utilized, and only when the medical device is not connected to a human body.

The Examiner's Action also relies on the teachings of *Wainwright*. *Wainwright* discloses an apparatus for the controlled administration of ozone, and shows, in Figure 1, that a blood purging apparatus 60 can be provided which is connected to a flask 82 that contains blood, and utilizing ozone to treat the blood contained within the flask 82.

However, and similar to the above-noted deficiencies of *Twardowski*, this reference does not disclose or otherwise suggest a replenishing solute circuit, as recited by Applicant's independent claim 3, nor does it disclose transporting a solution that contains ozone into an extracorporeal circuit to enter human blood vessels to kill microorganisms in the human body, as recited by claim 3. As such, it is submitted that Applicant's independent claim 3, and dependent claim 4, are *prima facie* patentably

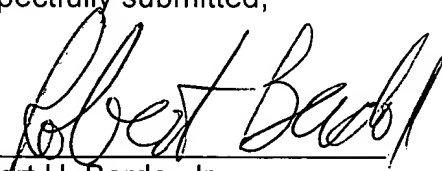
distinguishable over the cited references. It is requested that these claims be allowed and that these rejections be withdrawn.

It is submitted that this application is in condition for allowance. Such action and the passing of this case to issue are requested.

Should the Examiner feel that a conference would help to expedite the prosecution of the application, the Examiner is hereby invited to contact the undersigned counsel to arrange for such an interview.

Respectfully submitted,

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Date


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